

**EXHIBIT L - PAGE 1****Double-Blind, Placebo-Controlled, Clinical Study To Investigate The Effectiveness Of Glucosamine/Chondroitin Sulfate In The Treatment Of Patients With Osteoarthritis Of The Knee**

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*What kind of study is this, and why is it being done?*

This is an Internet-based research study of a food supplement, Glucosamine/Chondroitin Sulfate, in the treatment of osteoarthritis. Glucosamine and Chondroitin Sulfate are natural products extracted from foods such as beef and shellfish. They are nutritional products and are not regulated by the FDA. Studies have shown that these compounds are safe and may help symptoms of osteoarthritis.

The purpose of this study is to evaluate the effectiveness of a Glucosamine/Chondroitin Sulfate combination in the treatment of osteoarthritis of the knee. All participants will be monitored regularly for possible side effects by adverse event reporting. The effectiveness of the drug will be determined by assessing changes in pain scores. A total of approximately 200 people are expected to participate in this research study.

*Will there be any cost to me if I participate?*

There will be no financial charge to you for participating in this study. The study drug will be supplied to you free of charge.

*What will I have to do if I decide to participate?*

This study entails taking the study capsules (one three times per day) for 12 weeks. These will contain Glucosamine/Chondroitin Sulfate, and vitamin C as a preservative.

During the 12-week period arthritis pain will be evaluated by questionnaires every 2 weeks, filled out and submitted using the Internet. These take 5 - 10 minutes each. In addition we will ask you to keep a record of daily consumption of all other arthritis medications (e.g. Tylenol, Advil) and to report any possible side-effects. We will send you daily Email messages to enable you to do this.

*How do I know who the study investigators are ?*

The Primary Investigator is Timothy E. McAlindon MD MPH, Assistant Professor in Medicine, Boston University School of Medicine. The study is being run from Boston University School of Medicine and has received ethical approval from the Boston University Institutional Review Board. No sponsorship has been received from any manufacturer of the study investigational compound. This information can be corroborated by calling the Coordinator of the Institutional Review Board of Boston Medical Center at (617) 638-7266.

*How will the study investigators know who I am ?*

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The authenticity of participants is important for confidentiality and for the validity of the study. Therefore, we will ask you to participate in some simple steps to make sure that you are not being impersonated:

1. We will ask you to sign a hard copy of this consent form. This is a legal document. It asks you to provide your name, date of birth, address, a telephone number at which you can be contacted, and your email address.
2. We will issue you a unique login name and password by Email and conventional mail. A toll-free number will be provided so that any errors can be rectified immediately.
3. Before we send you the capsules, we will call you briefly on the telephone to make sure that we have the correct information, and that you are still interested in participating.

*Will any information identify me by name or will my name be given to anyone?*

We will treat all information that you give us, or that we determine from your records, in the strictest confidence. The information which you send us will for the exclusive use of this study and will not be released to any other party. Records which reveal your identity will be kept on a secure server or in a locked filing cabinet in the Arthritis Center, Boston University School of Medicine. No record will leave the study office or server with any information which directly identifies the participant. Study information which is collected will be analyzed and may be published, but this will not include your name.

*How will the study investigators know if I am eligible to participate in the study?*

We are seeking people aged over 50 years who have pain in their knees due to osteoarthritis. In order to find out if you qualify for the study we will take the following steps:

- i) We will ask questions about your knee symptoms
- ii) We will ask for your permission to write to your physician or hospital to obtain copies of your knee x-ray report
- iii) If you have any x-rays of your knees we will ask you to mail them to us.

We will pay for any costs incurred by requesting copies of x-ray reports or for mailing x-rays.

*Are there any reasons why I should not be in the study?*

Individuals aged less than 50 years, or those with very mild disease, may be considered ineligible. Similarly those who have had recent knee surgery or injections, or are already taking glucosamine or chondroitin or similar product, are ineligible.

*Is there anything which could happen to me if I participate?*

The oral ingestion of glucosamine and chondroitin sulfate has not been associated with any important side-effect or allergic response. These nutritional products are already widely available and widely use by the general public. Nevertheless, there is always potential for unexpected adverse events including hypersensitivity reactions. Any adverse event experienced during administration of the study drug will be described in detail and fully evaluated by the investigator.

*What happens if I have problems while I am in the study?*

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If you have any problems at any time during the study you may contact Timothy McAlindon MD (tuncalind@acs.bu.edu) at (800) 638-5180. You will be provided with any significant new information that becomes known during the course of the research which may effect your willingness to continue participation in the study.

*What am I going to get out of this if I agree to participate in this study?*

Studies like this are essential to developing new treatments for osteoarthritis, however, you may or may not receive any direct health benefit from participating in this study.

*Do I have to participate and can I change my mind even after I agree to be in the study?*

Your participation in this research study is entirely voluntary. If you do not wish to participate, or if you decide to enter the study and withdraw at any time later, there will be no penalty or loss of benefits to which you are otherwise entitled, and your future medical care will not be affected.

*What happens if I decide to withdraw from the study?*

If you decide to withdraw from the study you will be asked to provide a final questionnaire evaluation and to return unused study drug.

*Could I be withdrawn from the study without my permission?*

Under certain circumstances we may withdraw participants from the trial. These situations include accounts of adverse effects, difficulties with sticking to the dosage regimen or protocol.

*Whom do I call if I have any questions?*

If you have any questions regarding this research or your participation in it, please feel free to call Timothy McAlindon MD at (617) 638-5180.

You may obtain further information about your rights as a research subject by calling the Coordinator of the Institutional Review Board of Boston Medical Center at 638-7266. If any problems arise as a result of your participation in this research, including research-related injuries, please call the principal investigator, Timothy McAlindon MD at (617) 638-5180, immediately.

***Consent to Participate in Research***

You are not obligated to participate in this research. If you choose not to participate, your present and/or future medical care will not be affected in any way, and you will incur no penalty or loss of benefits to which you may otherwise be entitled. Also, if you participate, you may withdraw your consent and discontinue participation at any time without affecting your medical care or benefits to which you may otherwise be entitled.

I understand that in the event injury occurs resulting from the research procedures, medical treatment will be available at Boston Medical Center. However, no special arrangements will be made for compensation, or for payment for treatment solely because of my participation in this experiment. I understand that this paragraph is a statement of policy of Boston Medical Center, and of the policy of Boston University, and does not waive any of my legal rights.

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I have read the above description of this research study, and I understand it. I have been informed of the risks and benefits involved, and all of my questions have been answered to my satisfaction. Furthermore, I have been assured that any future questions I may have will also be answered by a member of the research team. I understand that I will receive a copy of this form.

I understand that I am free to withdraw this consent and discontinue participation in this research study at any time without prejudice. I voluntarily consent to my participation in the described research study.

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Signature of Patient

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Date

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Signature of Witness

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Date

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Please also provide the following information :

*Physician* from whom your knee x-rays, or x-ray report, are likely to be available:

Name :

Address:

*Hospital* from which your knee x-rays, or x-ray report, are likely to be available:

Name :

Address:

Consent form

I, the undersigned, authorize any physician or surgeon who has attended me, and any hospital where I was treated, to release to investigators at Boston University, knee radiographs, or radiographic reports, which were generated during the course of that treatment.

I understand that any such information received by Boston University will be kept confidential.

signature

please print full name

date

date of birth

address

Investigator :

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